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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,409	01/18/2002	Susumu Maruo	Q68143	2146

23373 7590 07/28/2005

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,409	MARUO ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.D

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. §1.114, the Amendment and Applicant's Arguments/Remarks and the request for extension of time (1 month-granted), all filed 07/08/05 is acknowledged.

Claims 1, 4-8 and 11-12 are pending. Claims 1 and 8 have been amended. Claims 1, 4-8 and 11-12 are rejected.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/08/05 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4-8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda *et al.* (US Pat. No. 5, 045,553) in view of Woo *et al.* (US Pat. No. 6,455,067 B1).

Ueda *et al.* teach a pharmaceutical composition for percutaneous drug absorption and percutaneous drug absorption promoter comprising a patch preparation comprising a support and a gel (ointment) wherein the gel is coated over the aluminum support in an amount or 38.3 mg per cm^2 and the thickness of the ethylene vinyl acetate (EVA) support film is 50 microns (see reference col. 7, lines 15-20 – Example 12). The gel patch preparation can further include an acrylic adhesive layer on the film (col. 7, lines 15-45). Ueda *et al.* teach that the pharmaceutical composition can be administered in various dosage forms. When the composition is in the form of a patch, the composition is spread over a support member (col. 3, lines 43-55). The composition may also be made up into ointments, such as Macrogol ointments, FAPG ointments, hydrophilic ointments, absorptive ointments, Carbopol gel ointments, etc (col. 3, lines 64-68). It is also possible to fill the composition in an appropriate container (to prevent adherence to clothes) and attach the container to the skin so that the composition can come into contact therewith or to coat a support member (as in tape preparations) with the composition to a certain

thickness and apply the whole to the skin (col. 4, lines 9). Furthermore, the composition can be made up into patches, for example, by spreading the composition over an appropriate support member (i.e., made of aluminum), and if necessary sealing with an absorption promoter film such as ethylene-vinyl acetate copolymer film (col. 4, lines 10-20). The Examples on cols. 7-9 further demonstrates the use of patch preparations comprising a support member and a gel (ointment) in various percentages, which read on the applicant's instantly claimed ranges.

Ueda *et al.* while teaching a pharmaceutical composition for percutaneous drug absorption and percutaneous drug absorption promoter comprising a patch preparation comprising a support and a gel (ointment) wherein the gel is coated over the aluminum support in an amount or 38.3 mg per cm^2 and the thickness of the ethylene vinyl acetate (EVA) support film is 50 microns (col. 7, lines 15-20 – Example 12), do not explicitly teach the degree of water vapor permeability of the support. It would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable amounts or ranges of water vapor permeability through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters. Moreover, generally differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claims are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Ueda *et al.* are lacking in the sense that they do not explicitly teach a support material comprising a copolymer of vinyl acetate and acrylic acid.

Woo *et al.* teach a transdermal patch comprising a synthetic polymer of *polyvinyl acetate-acrylic acid copolymer* used for strengthening the water retention, the processing and plasticity of the patch. The patch also contains various ointments, gels and support materials made of fabric cloth. The patch provides excellent dermal absorption and good skin adhesion without skin irritation (see reference column 6, lines 5-19); (col. 5, lines 3-13); (col. 6, lines 25-37).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined reference teachings of Woo *et al.* within Ueda *et al.* for the teaching of vinyl acetate/acrylic acid copolymers because Woo *et al.* teach a transdermal patch comprising a synthetic polymer of polyvinyl acetate-acrylic acid copolymer which functions to provide strengthening of water retention, processing and plasticity of the patch without influencing the effects of the patch. The expected result would be an effective skin patch with improved strengthening, processing and plasticizing capabilities.

Response to Arguments

Applicant's arguments filed 07/08/05 have been fully considered but they are not persuasive.

Applicant argued regarding the 35 U.S.C. §103(a) rejection of Claims 1, 4-8, 11 and 12 over Ueda et al. (US '553) in view of Woo et al. (US '067) stating the following:

One of ordinary skill in the art would not have been motivated to utilize the Woo et al. patch for a non-steroidal anti-inflammatory drug, such as a dihydropyridine compound disclosed

in Ueda et al., there is no motivation to combine Woo et al. and Ueda et al. The EVA film of Ueda does not correspond to the support of the present invention. The aluminum support does not have the properties of the support of the present invention, such as the water vapor permeability property, air permeability, modulus and stretching of 50% or more as in the present invention".

Applicant's arguments have been considered, but were not found persuasive. Ample motivation is provided by the prior art to use the combined reference teachings to obtain an effective pharmaceutical composition for percutaneous drug absorption. With regards to Applicant's claimed properties (i.e., water vapor & air permeability, modulus, etc.), it is the position of the Examiner, that it would have been deemed obvious to one of ordinary skill in the art to determine suitable amounts or ranges of water/air permeability and modulus through the use of routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art. Applicants have not demonstrated any unusual or surprising results, which accrue from the instant permeability and modulus ranges.

Applicant argued, "In addition, claims 1 and 8 are amended to recite that the support is impermeable to the ointment and that the ointment coated surface of the support directly contacts the skin. In contrast, Ueda teaches an aluminum support coated with an ointment and the ointment is covered with EVA film, wherein the EVA film is between the ointment and the skin. The EVA film of Ueda corresponds to an intermediate layer between an ointment coated surface of the support and the skin, which is avoided in the present invention. It is disclosed in the specification that without the intermediate layer, the ointment patch of the present invention further achieves improved adhesion to the skin".

Applicant's arguments have been considered, but were not found persuasive. The support of the prior art is functionally equivalent to the support of the instant invention, absent some unusual and/or unexpected results, brought about by the impermeability of the support to the ointment, as claimed. The penetration of the ointment of the prior art still results in the same effects desired by Applicant, and thus, the impermeability of the support to the ointment of the instant invention, does not impart a patentable difference. Applicant's argument that an 'intermediate layer is avoided in the present invention' is not persuasive since the instant claims utilize 'comprising' claim language and thus permits the presence of additional layers or ingredients, asides from those instantly recited.

Applicant argued, "Woo does not cure the deficiencies of Ueda. The copolymer of Woo is merely used as one of the additives incorporated into the solid; and not used in a film nor used as the support. Woo is also silent about the water vapor permeability."

Applicant's arguments were not found persuasive. Woo recognizes that it is well known to incorporate polyvinyl acetate-acrylic acid copolymer in a transdermal patch formulation, albeit the polyvinyl acetate-acrylic acid being one of the additives. The polyvinyl acetate-acrylic acid copolymer provides for strengthening the water retention, the processing and plasticity of the patch. While Woo is silent about water vapor permeability properties, it is obvious to one of ordinary skill in the art to determine suitable ranges of permeability through routine experimentation, to obtain an optimal outcome. No unexpected results are observed in the instant water vapor permeability amounts.

Applicant argued, "In addition, both the EVA film of Ueda and PVA component of Woo are permeable to the ointment, whereas the support film of the present invention is impermeable to the ointment."

This was not found persuasive, since as delineated above, the support of the prior art is equivalent to the support of the instant invention, absent a showing of some unusual and/or unexpected results, due to the impermeability of the support to the ointment, as claimed. The penetration of the ointment of the prior art still results in the same effects desired by Applicant, and thus, the impermeability of the support to the ointment of the instant invention, does not impart a patentable difference.

Applicant argued, "The polyvinyl acetate-acrylic acid copolymer of Woo is not cross-linked as in the present invention".

Admittedly, while the copolymer taught by Woo is not a cross-linked copolymer, Woo does in fact teach and recognize the art of incorporating polyvinyl acetate-acrylic acid copolymer in a transdermal patch preparation. The polyvinyl acetate-acrylic acid copolymer provides for beneficial effects, such as strengthening the water retention, the processing and plasticity of the patch.

In summary, ample motivation is provided by the prior art to obtain a patch preparation that offers excellent absorption, greater strength, improved processing and plasticity abilities. No significant patentable distinction has been observed between the instant invention and the prior art since the prior art teaches a similar composition comprising similar ingredients, used for the same field of endeavor and to solve the same problems as that desired by Applicant. Hence,

given the teachings of the prior art, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh H. N. Sheikh

Patent Examiner

Art Unit 1615

July 22, 2005